



SEP - 5 2001

3600 SW 47th Avenue  
 Gainesville, Florida 32608  
 TEL: 352/338-0440 FAX: 352/338-0662

**510(k) SUMMARY**

**APPLICANT:** Medical Device Technologies, Inc.  
 3600 SW 47<sup>th</sup> Avenue  
 Gainesville, FL 32608

**CONTACT:** Karl Swartz  
 Quality Assurance Manager

**TELEPHONE:** (352)338-0440  
 fax (352)338-0662

**TRADE NAMES:** MicroCruiser® Plus Introducer Set

**COMMON NAME:** Catheter introducers

**CLASSIFICATION NAME:** §870.1340-Introducer, Catheter

**SUBSTANTIAL EQUIVALENCE:**

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Cook, Inc.	MicroPuncture	Pre-Ammendment

**DESCRIPTION OF DEVICE:**

The MicroCruiser® Plus Introducer Set is comprised of an .018" diameter guidewire, a guidewire introducer needle, and a coaxial introducer that has a diameter suitable for catheter introduction and placement. The introducer tubing is made from biocompatible polyurethane that has been used extensively in both short and long term catheters. The introducers are provided in the following French sizes: 3 (Inner)/4 (Outer), 3 (Inner)/5 (Outer), and 4 (Inner)/6 (Outer), and in lengths of 10 cm.

**INDICATIONS FOR USE:**

The MicroCruiser® Plus Introducer Set is intended for use in the introduction and placement of guidewires and/or catheters.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Karl Swartz  
Medical Device Technologies, Inc.  
3600 SW 47<sup>th</sup> Avenue  
Gainesville, FL 32608

Re: K011790  
MicroCruiser® Plus Introducer Set  
Regulation Number: 870.1340  
Regulatory Class: II (two)  
Product Code: DYB  
Dated: June 7, 2001  
Received: June 8, 2001

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

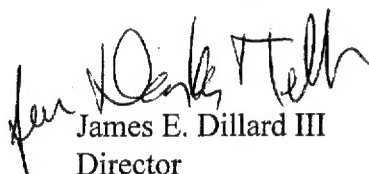
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have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the printed name.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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Jainesville, Florida 32608  
TEL: 352/338-0440 FAX: 352/338-0662

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510(k) Number (if known): K011790


Device Name: MicroCruiser® Plus Introducer Set

Indications for Use:

The MicroCruiser® Plus Introducer Set is intended for use in the introduction and placement of guidewires and/or catheters..

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K011790

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

